K101305

OCT 29 2010

# 510(k) SUMMARY

## ARK™ Lamotrigine Assay
## ARK™ Lamotrigine Calibrator
## ARK™ Lamotrigine Control

## 510(k) SUMMARY

OCT 2 9 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K101305.

**807.92 (a)(1): Name:** **ARK Diagnostics, Inc.**


**Address:** 1190 Bordeaux Drive
Sunnyvale, CA 94089

**Owner Operator Number:** 10027663
**Establishment Registration:** 3005755244

**Phone:** (408) 747-0700
**FAX:** (408) 747-0783
**Contact:** Johnny Valdez – (408) 747-0706
President


**Date prepared:** October 20, 2010

**807.92 (a)(2): Device name- trade name and common name, and classification**

Trade name: ARK™ Lamotrigine Assay
ARK™ Lamotrigine Calibrator
ARK™ Lamotrigine Control

Common Name: Homogeneous Enzyme Immunoassay

Classification: 21 CFR 862.3350 NWM Diphenylhydantoin Test System; Class II
(21 CFR 862.3200 DLJ, 21 CFR 862.3280 LAS)

**807.92 (a)(3): Identification of the legally marketed predicate device**

QMS® Lamotrigine, calibrators and controls (K062966)

**807.92 (a)(4): Device Description**

The ARK Lamotrigine Assay is a homogeneous immunoassay based on competition between drug in the specimen and lamotrigine labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for binding to the antibody reagent. As the latter binds antibody, enzyme activity decreases. In the presence of drug from the specimen, enzyme activity increases and is directly proportional to the drug concentration. Active enzyme converts the coenzyme nicotinamide adenine dinucleotide (NAD) to NADH that is measured spectrophotometrically as a rate of change in absorbance. Endogenous serum G6PDH does not interfere with the results because the coenyzme NAD functions only with the bacterial enzyme used in the assay.

The ARK Lamotrigine Assay consists of reagents R1 anti-lamotrigine polyclonal antibody with substrate and R2 lamotrigine labeled with bacterial G6PDH enzyme. The ARK Lamotrigine Calibrator consists of a six-level set to calibrate the assay, and the ARK Lamotrigine Control consists of a three-level set used for quality control of the assay.

**807.92 (a)(5): Intended Use / Indications for Use**

The ARK™ Lamotrigine Assay is a homogeneous enzyme immunoassay intended for the quantitative determination of lamotrigine in human serum or plasma on automated clinical chemistry analyzers. Lamotrigine concentrations can be used as an aid in management of patients treated with lamotrigine.

The ARK™ Lamotrigine Calibrator is intended for use in calibration of the ARK Lamotrigine Assay.

The ARK™ Lamotrigine Control is intended for use in quality control of the ARK Lamotrigine Assay.

**807.92 (a)(6): Technological Similarities and Differences to the Predicate**

**SUBSTANTIAL EQUIVALENCE COMPARATIVE CHART**

**Comparison between the ARK™ Lamotrigine Assay and the** QMS® Lamotrigine Assay

| **Characteristic** | **Device**<br>ARK™ Lamotrigine Assay | **Predicate**<br>QMS® Lamotrigine K062966 |
|---|---|---|
| Intended Use | The ARK™ Lamotrigine Assay is intended for the quantitative determination of lamotrigine in human serum or plasma on automated clinical chemistry analyzers. | The QMS Lamotrigine is intended for the quantitative determination of lamotrigine in human serum or plasma on automated clinical chemistry analyzers. |
| Indications for Use | Lamotrigine concentrations can be used as an aid in management of patients treated with lamotrigine. | Lamotrigine concentrations can be used as an aid in management of patients treated with lamotrigine. |
| Sample | Serum or plasma | Serum or plasma |
| Methodology | Homogenous enzyme immunoassay (EIA) | Homogeneous particle-enhanced turbidimetric immunoassay (particle agglutination) |
| Reagent Components | Two (2) reagent system:<br>• Anti-Lamotrigine Antibody/Substrate Reagent (R1) containing rabbit polyclonal antibodies to lamotrigine, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, preservatives, and stabilizers<br>• Enzyme Reagent (R2) containing lamotrigine labeled with bacterial G6PDH, buffer, bovine serum albumin, preservatives, and stabilizers | Two (2) reagent system:<br>• Anti-Lamotrigine Antibody Reagent (R1) in buffers containing stabilizers with sodium azide<br>• Lamotrigine-coated Microparticle Reagent (R2) in buffer containing stabilizers with sodium azide |
| Platform required | Automated clinical chemistry analyzer | Automated clinical chemistry analyzer |
| Accessory reagents | Calibrators (six levels) and controls (three levels) | Calibrators (six levels) and controls (three levels) |
| Testing environment | Routine clinical laboratory | Routine clinical laboratory |
| Reagent condition and storage | Liquid, 2-8° C | Liquid, 2-8° C |

**807.92 (b)(1) and 807.92 (b)(2):**
**Brief Description of Nonclinical and Clinical Data**

*Limit of Quantitation (LOQ)*

The LOQ of the ARK Lamotrigine Assay was determined according to CLSI EP17-A and is defined as the lowest concentration for which acceptable inter-assay precision and recovery is observed (≤20% CV with ±15% recovery). The LOQ was determined to be 0.85 µg/mL, and may depend on analyzer-specific performance.

*Assay Range*

The range of the assay is 0.85 to 40.00 µg/mL. Report results below this range as <0.85 µg/mL or below the analyzer-specific lower LOQ established in your laboratory. Report results above this range as >40.00 µg/mL or above the analyzer-specific upper LOQ established in your laboratory.

Specimens testing initially above the assay range may be diluted in Calibrator A and retested. Multiply the assay result by the dilution factor to obtain the concentration of lamotrigine in the undiluted specimen.

*Recovery*

Accuracy (analytical recovery) was performed by adding concentrated lamotrigine drug into human serum negative for lamotrigine. A stock concentrate of highly pure lamotrigine was added volumetrically to human serum negative for lamotrigine, representing drug concentrations across the assay range. Six replicates of each sample were assayed on an automated clinical chemistry analyzer. The results were averaged and compared to the target concentration and percent recovery calculated. Results are shown below.

$$\% \text{ Recovery} = 100 \times \frac{\text{Mean recovered concentration}}{\text{Theoretical concentration}}$$

| Theoretical Concentration (µg/mL) | Mean Recovered Concentration (µg/mL) | Percent Recovery |
|---|---|---|
| 0.85 | 0.84 | 98.2 |
| 1.00 | 0.99 | 99.2 |
| 2.50 | 2.48 | 99.3 |
| 5.00 | 5.25 | 105.1 |
| 11.00 | 10.97 | 99.7 |
| 15.00 | 14.80 | 98.7 |
| 30.00 | 29.16 | 97.2 |
| 40.00 | 38.33 | 95.8 |

Mean percent recovery: 99.2

*Linearity*

Linearity studies were performed as suggested in CLSI/NCCLS Protocol EP6-A. A 48.00 µg/mL serum sample was prepared and dilutions were made proportionally with human serum negative for lamotrigine. Lamotrigine concentrations ranged from 1.00 to 48.00 µg/mL. Linearity at specific dilutions was considered acceptable if the percent difference was ±10% between the predicted 1st and 2nd order regressed values. Results are shown below.

| Estimated Value (µg/mL) | Results (µg/mL) | 1st Order Predicted Results | 2nd Order Predicted Results | % Difference (Acceptance Criteria: ±10%) |
|---|---|---|---|---|
| 1.00 | 0.96 | 1.13 | 1.21 | 7.1 |
| 2.00 | 2.08 | 2.11 | 2.17 | 3.1 |
| 4.00 | 4.16 | 4.06 | 4.10 | 0.9 |
| 8.00 | 8.18 | 7.97 | 7.96 | -0.1 |
| 12.00 | 12.01 | 11.88 | 11.83 | -0.4 |
| 16.00 | 16.18 | 15.78 | 15.72 | -0.4 |
| 24.00 | 22.78 | 23.60 | 23.53 | -0.3 |
| 32.00 | 30.84 | 31.41 | 31.39 | -0.1 |
| 40.00 | 40.13 | 39.23 | 39.30 | 0.2 |
| 48.00* | 46.88 | 47.04 | 47.27 | 0.5 |

*Concentration exceeds the reportable limit.

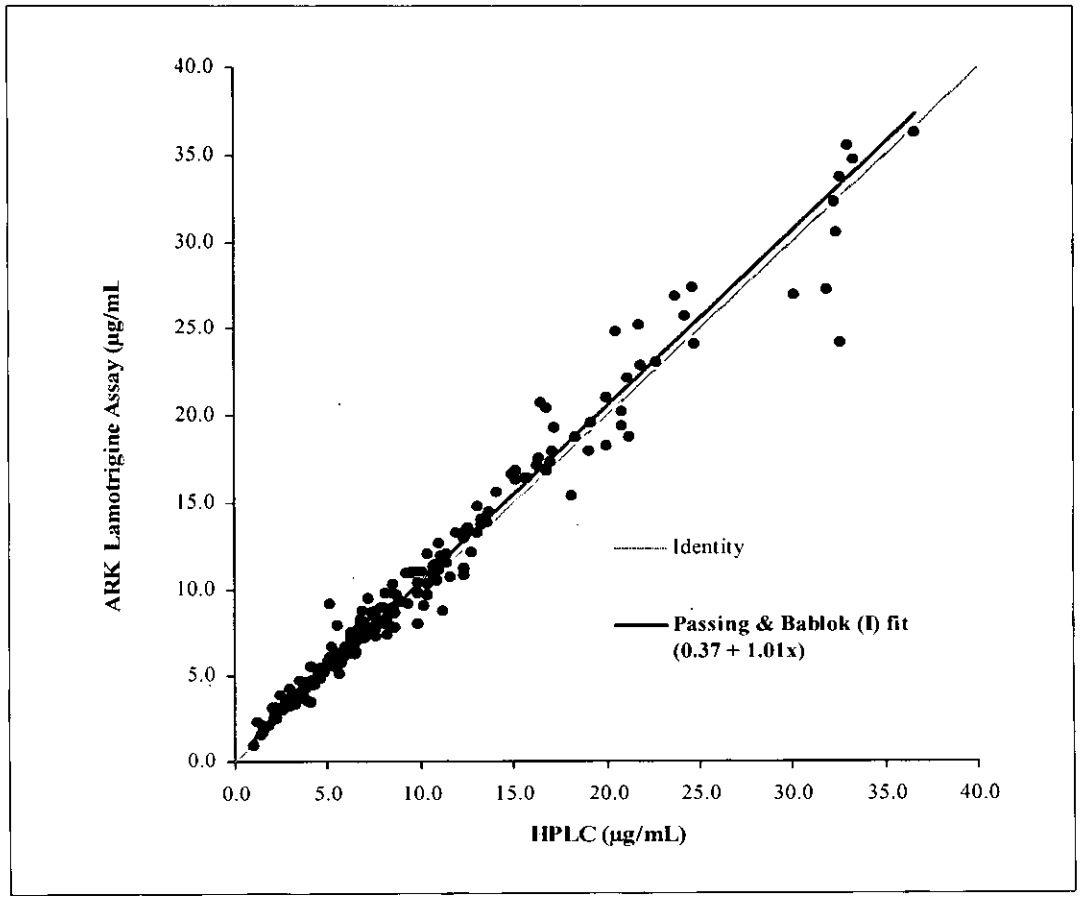
*Method Comparison*

Correlation studies were performed using CLSI/NCCLS Protocol EP9-A2. Results from the ARK Lamotrigine Assay on the Roche/Hitachi 917 system were compared with results from high performance liquid chromatography (HPLC, Study 1) and a turbidimetric immunoassay (Study 2).

Study 1

Lamotrigine concentrations by HPLC ranged 1.00 to 36.70 µg/mL. ARK lamotrigine values ranged 0.97 to 36.32 µg/mL. Results of the Passing-Bablok[9] regression analysis for the study are shown below (with 95% confidence limits).

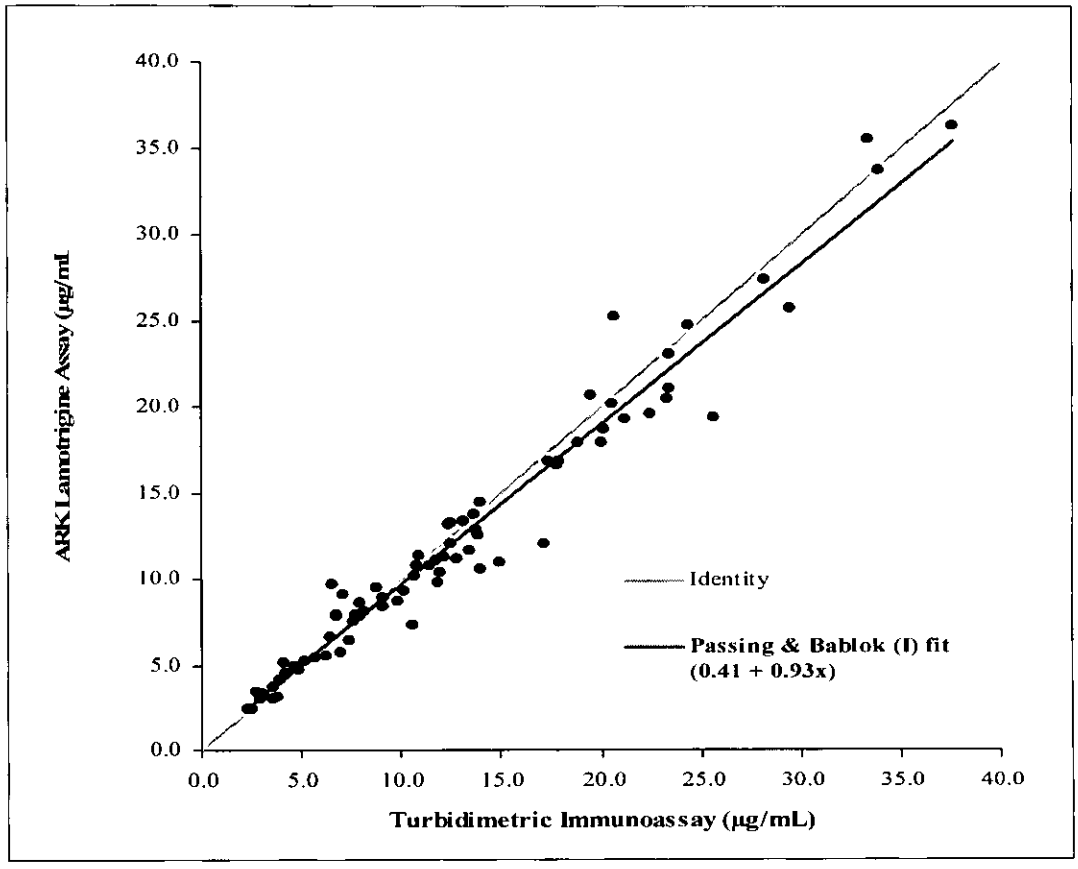
| | | |
|---|---|---|
| Slope | 1.01 | (0.99 to 1.03) |
| y-intercept | 0.37 | (0.22 to 0.55) |
| Correlation Coefficient ($r^2$) | 0.97 | (0.96 to 0.98) |
| Number of Samples | 193 | |



Study 2

Lamotrigine concentrations by the turbidimetric immunoassay ranged from 2.28 µg/mL to 37.70 µg/mL. ARK lamotrigine values ranged 2.51 to 36.32 µg/mL. Results of the Passing-Bablok[9] regression analysis for the study are shown below (with 95% confidence limits).

| | | |
|---|---|---|
| Slope | 0.93 | (0.89 to 0.97) |
| y-intercept | 0.41 | (0.07 to 0.74) |
| Correlation Coefficient ($r^2$) | 0.96 | (0.94 to 0.97) |
| Number of Samples | 77 | |



*Precision*

Precision was determined as described in CLSI/NCCLS Protocol EP5-A2. Tri-level controls and three human serum pooled specimens containing lamotrigine were used in the study. Each level was assayed in quadruplicate twice a day for 20 days. Each of the runs per day was separated by at least two hours. The within run, between day, total SD, and percent CVs were calculated. Results are shown below. Acceptance criteria: ≤10% total CV.

| Sample | N | Mean (µg/mL) | Within Run | | Between Day | | Total | |
|---|---|---|---|---|---|---|---|---|
| | | | SD | CV (%) | SD | CV (%) | SD | CV (%) |
| ARK Lamotrigine Control | | | | | | | | |
| LOW | 160 | 2.08 | 0.07 | 3.4 | 0.05 | 2.5 | 0.08 | 4.1 |
| MID | 160 | 11.70 | 0.42 | 3.6 | 0.28 | 2.4 | 0.49 | 4.2 |
| HIGH | 160 | 24.23 | 0.99 | 4.1 | 1.06 | 4.4 | 1.47 | 6.1 |
| Calibrator/Control Matrix | 40 | 38.04 | 2.05 | 5.4 | 0.95 | 2.5 | 2.27 | 6.0 |
| Human Serum | | | | | | | | |
| LOW | 160 | 2.41 | 0.08 | 3.5 | 0.09 | 3.7 | 0.12 | 5.2 |
| MID | 160 | 10.75 | 0.41 | 3.8 | 0.42 | 3.9 | 0.59 | 5.5 |
| HIGH | 160 | 25.84 | 1.33 | 5.2 | 1.12 | 4.3 | 1.88 | 7.3 |
| Pooled Human Serum | 40 | 38.24 | 2.78 | 7.3 | 0.61 | 1.6 | 3.38 | 8.8 |

*Interfering Substances*

Interference studies were conducted using CLSI/NCCLS Protocol EP7-A2 as a guideline. Clinically high concentrations of the following potentially interfering substances in serum with known levels of lamotrigine (approximately 3 and 15 µg/mL) were evaluated. Each sample was assayed using the ARK Lamotrigine Assay, along with a serum control of lamotrigine. Measurement of lamotrigine resulted in ≤10% error in the presence of interfering substances at the levels tested.

| | | Percentage Recovery | |
|---|---|---|---|
| **Interfering Substance** | **Interferent Concentration** | **3 µg/mL Lamotrigine** | **15 µg/mL Lamotrigine** |
| Albumin | 12 g/dL | 101.5 | 103.4 |
| Bilirubin - conjugated | 70 mg/dL | 93.6 | 102.6 |
| Bilirubin - unconjugated | 70 mg/dL | 97.1 | 105.0 |
| Cholesterol | 623 mg/dL | 98.9 | 103.8 |
| Gamma-Globulin | 12 g/dL | 106.8 | 104.4 |
| Hemoglobin | 1000 mg/dL | 98.2 | 97.0 |
| Intralipid® | 1000 mg/dL | 94.5 | 94.3 |
| Rheumatoid Factor | 1100 IU/mL | 107.3 | 108.9 |
| Triglycerides | 618 mg/dL | 101.7 | 104.0 |
| Uric Acid | 30 mg/dL | 101.0 | 99.6 |

*Specificity*

Lamotrigine's major metabolite, medications that may be routinely co-administered with lamotrigine and other anti-epileptic drugs were tested to determine whether these compounds affect the quantitation of lamotrigine concentrations using the ARK Lamotrigine Assay. High levels of these compounds were spiked into serum pools containing low (3 µg/mL) and high (15 µg/mL) therapeutic levels of lamotrigine. The samples were analyzed and the lamotrigine concentrations of samples containing interferent were compared to the serum control.

*Metabolites*

Lamotrigine is metabolized predominantly by UDP-glucuronyltransferase to form a pharmacologically inactive metabolite, 2-N-glucuronide. Lamotrigine-2-N-methyl has been detected in human plasma by HPLC and capillary electrophoresis. Other minor metabolites, lamotrigine-2-N-oxide, and lamotrigine-5-N-glucuronide have been proposed. Lamotrigine-2-N-glucuronide, Lamotrigine-2-N-methyl and Lamotrigine-2-N-oxide metabolites were tested for cross-reactivity. These metabolites were spiked into two separate samples each containing low and high lamotrigine concentrations of 3 and 15 µg/mL, respectively.

| Metabolite* | Metabolite Concentration (µg/mL) | Percentage Cross-Reactivity Lamotrigine (3 µg/mL) | Lamotrigine (15 µg/mL) |
|---|---|---|---|
| Lamotrigine-2-N-glucuronide | 50.0 | 2.41 | 1.86 |
| | 25.0 | 2.57 | 1.09 |
| | 12.5 | 2.91 | 1.92 |
| | 9.0 | 2.15 | 1.57 |
| Lamotrigine-2-N-methyl | 400.0 | 0.04 | 0.21 |
| | 200.0 | 0.07 | 0.02 |
| | 80.0 | 0.10 | 0.24 |
| Lamotrigine-2-N-oxide | 80 | 3.69 | 3.63 |
| | 40 | 3.94 | 3.64 |
| | 20 | 3.72 | 3.14 |
| | 10 | 3.88 | 1.30 |

* The literature suggests there is weak evidence for the presence of minor metabolites in human plasma.

*Drug Interference*

Lamotrigine-selective antibody did not crossreact with most other anti-epileptic or coadministered drugs tested. Due to structural similarities with lamotrigine, high trimethoprim levels may interfere. A high concentration of each compound was spiked into normal human serum with known levels of lamotrigine (approximately 3 and 15 µg/mL) and assayed along with a serum control of lamotrigine. Measurement of lamotrigine resulted in ≤10% error in the presence of drug compounds at the levels tested.

| Compound | Conc. Tested (µg/mL) | Percentage Recovery | |
|---|---|---|---|
| | | 3 µg/mL Lamotrigine | 15 µg/mL Lamotrigine |
| Acetaminophen | 200 | 103.7 | 99.1 |
| Acetazolamide | 100 | 101.2 | 99.2 |
| Acetylsalicylic acid | 1000 | 100.8 | 100.7 |
| Amikacin | 100 | 95.7 | 97.0 |
| Amitriptyline | 20 | 99.0 | 97.9 |
| Amoxapine | 40 | 104.7 | 101.2 |
| Amphotericin B | 100 | 94.0 | 91.6 |
| Ampicillin | 100 | 97.7 | 94.1 |
| Ascorbic Acid | 100 | 98.5 | 94.4 |
| Baclofen | 100 | 95.8 | 90.9 |
| Buproprion | 40 | 98.8 | 106.2 |
| Caffeine | 100 | 101.3 | 103.2 |
| Carbamazepine | 120 | 104.3 | 103.2 |
| Carbamazepine-10, 11 epoxide | 120 | 101.7 | 99.0 |
| 10-Hydroxy carbamazepine | 100 | 96.2 | 94.3 |
| Chloramphenicol | 250 | 103.7 | 98.4 |
| Chlorpromazine | 20 | 97.2 | 95.0 |
| Citalopram | 20 | 98.0 | 97.5 |
| Clobazam | 100 | 103.4 | 105.6 |
| Clonazepam | 20 | 97.6 | 96.4 |
| Cyclosporin A | 40 | 101.7 | 99.4 |
| Diazepam | 20 | 101.1 | 97.7 |
| Digoxin | 80 | 103.4 | 97.6 |
| Doxepin | 20 | 101.6 | 103.1 |
| Erythromycin | 200 | 103.6 | 103.9 |
| Ethanol | 4000 | 94.0 | 98.2 |
| Ethotoin | 100 | 101.3 | 101.9 |
| Ethosuximide | 250 | 101.0 | 96.4 |
| Felbamate | 250 | 103.0 | 101.4 |
| Fluoxetine | 20 | 102.2 | 97.0 |
| Furosemide | 100 | 99.8 | 97.1 |
| Gentamicin | 100 | 99.8 | 98.6 |

| Compound | Conc. Tested (µg/mL) | Percentage Recovery | |
|---|---|---|---|
| | | 3 µg/mL Lamotrigine | 15 µg/mL Lamotrigine |
| Haloperidol | 20 | 104.1 | 100.3 |
| Heparin | 200 U/mL | 99.0 | 100.5 |
| Ibuprofen | 500 | 101.6 | 96.2 |
| Imipramine | 20 | 99.6 | 97.7 |
| Kanamycin B | 200 | 98.5 | 100.5 |
| Gabapentin | 200 | 103.8 | 98.1 |
| Levetiracetam | 400 | 103.6 | 101.9 |
| Lidocaine | 100 | 101.6 | 101.8 |
| Lincomycin | 1000 | 106.0 | 99.7 |
| Mephenytoin | 100 | 95.7 | 103.9 |
| Mesoridazine | 40 | 97.6 | 101.7 |
| Methicillin | 250 | 95.2 | 99.4 |
| Naproxen | 600 | 97.3 | 104.8 |
| Neomycin | 1000 | 100.8 | 101.6 |
| Niacin | 100 | 97.8 | 105.8 |
| Nitrazepam | 20 | 101.5 | 103.9 |
| Nortriptyline | 20 | 96.6 | 104.9 |
| Olanzapine | 20 | 99.5 | 102.2 |
| Oxcarbazepine | 200 | 97.3 | 100.5 |
| Paroxetine | 40 | 101.6 | 100.0 |
| 2-phenyl-ethyl-malonamide (PEMA) | 1000 | 100.1 | 100.9 |
| Penicillin V | 100 | 100.4 | 101.4 |
| Perphenazine | 100 | 99.5 | 103.2 |
| Phenobarbital | 200 | 101.0 | 98.9 |
| Phenytoin | 200 | 100.0 | 100.8 |
| Pregabalin | 200 | 99.6 | 98.4 |
| Primidone | 100 | 98.7 | 102.5 |
| Procainamide | 100 | 100.6 | 101.9 |
| Prochlorperazine | 40 | 99.4 | 90.3 |
| Ranitidine | 100 | 104.0 | 97.8 |
| Rifampin | 100 | 101.6 | 97.7 |
| Risperidone | 20 | 98.0 | 100.2 |
| Sertraline | 100 | 101.5 | 101.9 |

| Compound | Conc. Tested (µg/mL) | Percentage Recovery | |
|---|---|---|---|
| | | 3 µg/mL Lamotrigine | 15 µg/mL Lamotrigine |
| Spectinomycin | 100 | 97.7 | 103.1 |
| Stiripentol | 100 | 102.3 | 101.6 |
| Sulfamethoxazole | 400 | 99.2 | 99.2 |
| Theophylline | 200 | 98.7 | 97.9 |
| Thioridazine | 20 | 102.9 | 101.3 |
| Tobramycin | 100 | 98.8 | 96.9 |
| Tiagabine | 200 | 100.9 | 97.8 |
| Topiramate | 250 | 100.3 | 96.7 |
| Valproic Acid | 600 | 100.8 | 96.8 |
| Vancomycin | 250 | 96.5 | 95.0 |
| Vigabatrin | 150 | 97.8 | 101.0 |
| Zonisamide | 400 | 97.9 | 99.6 |

*Drug that Cross-Reacts*

Cross-reactivity of the antibody to trimethoprim at the following concentration was tested. A high concentration was spiked into normal human serum with known levels of lamotrigine (approximately 3 and 15 µg/mL) and assayed along with a serum control of lamotrigine. The results are shown below.

| Trimethoprim (µg/mL) | Percent Cross-Reactivity | | Percent Recovery | |
|---|---|---|---|---|
| | Lamotrigine (3 µg/mL) | Lamotrigine (15 µg/mL) | Lamotrigine (3 µg/mL) | Lamotrigine (15 µg/mL) |
| 40.0 | 4.4 | 3.0 | 156.0 | 108.0 |

Care should be taken when interpreting ARK Lamotrigine results if trimethoprim is also being administered to the patient.

*Anticoagulants*

Studies were conducted to determine the performance characteristics of the assay for both serum and plasma samples containing lamotrigine.

The results indicate that there is no significant difference between the recovery of lamotrigine in serum or plasma.

*Sample Stability*

Serum specimens were shown to be stable for at least six (6) months frozen, at least fifty (50) hours at room temperature (22°C), at least thirty-seven (37) days when refrigerated (2-8°C) and after three (3) successive freeze/thaw cycles.

*On-Board Stability*

Calibration Curve Stability:
Calibration curve stability for a period of 30 days is supported by data.

Reagent on-board stability:
Reagents were effective when stored after transfer to analyzer specific reagent containers for up to at least 30 days as supported data. In-use stability of calibrator and controls was also demonstrated.

Accelerated OPEN stability of calibrators and controls:
Calibrators and controls were shown to be stable OPEN in accelerated stability at 37°C for seven (7) days. Once opened vials may be stored at 2-8°C for 12 months.

*Traceabiliity of Calibrators and Controls*

There is no internationally recognized standard for lamotrigine. ARK Lamotrigine Calibrators and ARK Lamotrigine Controls are prepared by gravimetric dilution of high purity lamotrigine into a synthetic proteinaceous matrix free of lamotrigine.

The calibrator/control matrix was shown to be equivalent to human serum with supporting data.

**807.92 (b)(3): Conclusions from Nonclinical Testing**

The ARK Lamotrigine Assay, the ARK Lamotrigine Calibrator and the ARK Lamotrigine Control are substantially equivalent to the QMS Lamotrigine Assay system. The ARK Lamotrigine Assay system was shown to be safe and effective for its intended use based on performance studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

OCT 29 2010

ARK Diagnostics, Inc.
c/o Dr. Kenneth Kasper
Executive Director, Quality & Regulatory Affairs
1190 Bordeaux Drive
Sunnyvale, CA 94089

Re: k101305
Trade Name: ARK™ Lamotrigine Assay, ARK™ Lamotrigine Calibrator, and ARK™ Lamotrigine Control

Regulation Number: 21 CFR 862.3350
Regulation Name: Diphenylhydantoin Test System.
Regulatory Class: Class II
Product Codes: ORH, DLJ, LAS
Dated: October 28, 2010
Received: October 29, 2010

Dear Dr. Kasper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

**510(K) Number (if known):** k101305 OCT 2 9 2010

**Device Name:**

ARK™ Lamotrigine Assay
ARK™ Lamotrigine Calibrator
ARK™ Lamotrigine Control

**Indications for Use:**

The ARK™ Lamotrigine Assay is a homogeneous enzyme immunoassay intended for the quantitative determination of lamotrigine in human serum or plasma on automated clinical chemistry analyzers.

Lamotrigine concentrations can be used as an aid in management of patients treated with lamotrigine.

The ARK™ Lamotrigine Calibrator is intended for use in calibration of the ARK Lamotrigine Assay.

The ARK™ Lamotrigine Control is intended for use in quality control of the ARK Lamotrigine Assay.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k101305